

Preliminary Amendment
U.S. Patent Application No. 10/544,250

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Currently Amended) ~~Pharmaceutical~~ A pharmaceutical composition, ~~characterised in that it contains one or more~~ comprising at least one anticholinergic, ~~[[s]]~~ [[~~(1)~~]] in combination with ~~one or more~~ at least one soluble TNF receptor fusion protein ~~[[s]],~~ [[~~(2)~~]] wherein at least one of the at least one anticholinergic and the at least one soluble TNF receptor fusion protein is optionally in the form of ~~the~~ individual optical isomers, mixtures ~~thereof~~ or racemates ~~thereof~~, ~~and~~ is optionally in the form of ~~the~~ pharmacologically acceptable acid addition salts thereof, and is optionally in the form of ~~the~~ solvates or hydrates ~~and optionally together with a pharmaceutically acceptable excipient.~~

2. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to claim 1, ~~characterised in that 1~~ wherein at least one anticholinergic of the composition is selected from among the the group consisting of tiotropium salts, oxitropium salts, ~~[[or]]~~ and ipratropium salts, ~~preferably tiotropium salts.~~

3. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to claim 2, ~~characterised in that 1 is present in the form of the~~ wherein at least one anticholinergic in the composition comprises at least one of a chloride, bromide, iodide, methanesulphonate, ~~[[or]]~~ and para-toluenesulphonate, ~~preferably in the form of the bromide.~~

4. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to ~~claims 1, 2 or 3,~~ claim 1, ~~characterised in that 2 is~~ wherein the at least one soluble TNF receptor fusion protein is an etanercept or lenercept.

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5. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to claim 4, ~~characterised in that 2 is~~ wherein the at least one soluble TNF receptor fusion protein is an etanercept.

6. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to ~~one of claims 1 to 5, characterised in that the active substances 1 and 2~~ claim 1, wherein the at least one anticholinergic and the at least one soluble TNF receptor fusion protein are present in the composition either together in a single formulation or in two separate formulations.

7. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to ~~one of claims 1 to 6, characterised in that~~ claim 1, wherein the weight ratios of ~~1 to 2~~ the at least one anticholinergic and the at least one soluble TNF receptor fusion protein are in the range from 1:2000 to 1:1, ~~preferably from 1:1000 to 1:5.~~

8. (Currently Amended) ~~Pharmaceutical composition according to one of claims 1 to 7, characterised in that a single administration corresponds to a dose of the active substance combination 1 and 2 of~~ A method of administering a pharmaceutical composition comprising:
providing a pharmaceutical composition according to claim 1; and
administering the pharmaceutical composition at a selected dosage such that the at least one anticholinergic and the at least one soluble TNF receptor fusion protein in the administered composition is in the range from 1 µg to 10000µg, preferably from 10 to 5000µg.

9. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to ~~one of claims 1 to 8, characterised in that it is in the form of~~ claim 1, wherein the composition is a formulation suitable for inhalation.

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10. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to claim 9, ~~characterised in that it~~ wherein the composition is a formulation selected from ~~among~~ the group consisting of inhalable powders, ~~and~~ inhalable solutions, ~~or~~ and suspensions.

11. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to claim 10, ~~characterised in that it is~~ wherein the composition is an inhalable powder which contains ~~1 and 2~~ the at least one anticholinergic and the at least one soluble TNF receptor fusion protein in admixture with ~~suitable~~ at least one physiologically acceptable excipient[[s]] selected from ~~among~~ the group consisting of monosaccharides, disaccharides, oligo[[-]]saccharides, and polysaccharides, polyalcohols, salts, ~~or mixtures of these excipients with one another and~~ mixtures thereof.

12. (Currently Amended) ~~Inhalable~~ An inhalable powder comprising the pharmaceutical composition according to claim 11, ~~characterised in that the~~ wherein the at least one physiologically acceptable excipient has a maximum mass mean aerodynamic diameter of up to 250µm, ~~preferably between 10 and 150µm~~.

13. (Currently Amended) ~~Capsules, characterised in that they contain~~ A capsule containing an inhalable powder according to claim 11 ~~or 12~~.

14. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to claim 10, ~~characterised in that it~~ wherein the composition is an inhalable powder which contains only the ~~active substances 1 and 2 as its ingredients~~ at least one anticholinergic and the at least one soluble TNF receptor fusion protein.

15. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to claim 10, ~~characterised in that it~~ wherein the composition is [[a]] an inhalable solution or

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suspension which contains a solvent comprising one of water, ethanol or a mixture of water and ethanol as solvent.

16. (Currently Amended) ~~Inhalable~~ An inhalable solution or suspension comprising the pharmaceutical composition according to claim 15, ~~characterised in that wherein~~ the pH of the inhalable solution or suspension is from 2-7, preferably 2-5.

17. (Currently Amended) ~~Use of a capsule according to claim 13 in an inhaler, preferably in a Handihaler.~~ A method of providing a dosage of an inhalable powder comprising: providing a capsule containing an inhalable powder according to claim 11; and administering a dosage of the inhalable powder in the capsule using an inhaler.

18. (Currently Amended) ~~Use of an inhalable solution according to one of claims 15 or 16 for nebulising in a suitable inhaler.~~ A method of providing a dosage of an inhalable solution comprising:
providing an inhalable solution comprising a pharmaceutical composition according to claim 10 and a solvent comprising one of water, ethanol or a mixture of water and ethanol; and
administering a dosage of the inhalable solution by nebulizing the inhalable solution in an inhaler.

19. (Currently Amended) ~~Use of a composition according to one of claims 1 to 16 for preparing a medicament for treating inflammatory or obstructive diseases of the respiratory tract.~~ A method of preparing a medicament for treating inflammatory or obstructive diseases of the respiratory tract, the method comprising providing a pharmaceutical composition according to claim 1.

20. (New) The pharmaceutical composition of claim 1, further comprising a pharmaceutically acceptable excipient.

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21. (New) The pharmaceutical composition according to claim 1, wherein the weight ratios of the at least one anticholinergic and the at least one soluble TNF receptor fusion protein are in the range from 1:1000 to 1:5.

22. (New) The method of claim 8, wherein the pharmaceutical composition is administered at a selected dosage such that the at least one anticholinergic and the at least one soluble TNF receptor fusion protein in the administered composition is in the range from 10 µg to 5000µg.

23. (New) The inhalable powder according to claim 12, wherein the at least one physiologically acceptable excipient has a maximum mass mean aerodynamic diameter of between 10 and 150µm.

24. (New) The inhalable solution or suspension of claim 16, wherein the pH of the inhalable solution or suspension is from 2-5.